(7) Patient rights:
(A) The patient has the right to considerate and respectful service.
(B) The patient has the right to obtain service without regard to race, creed, national origin, sex, age, disability, diagnosis or religious affiliation.
(C) Subject to applicable law, the patient has the right to confidentiality of all information pertaining to his/her medical equipment and service. Individuals or organizations not involved in the patient's care may not have access to the information without the patient's written consent.
(D) The patient has the right to a timely response to his/her request for home medical equipment services.
(E) The patient has the right to select the home medical equipment supplier of his/her choice.
(F) The patient has the right to voice grievances without fear of termination of service or other reprisals.
(G) The patient has the right to expect reasonable continuity of service.
(H) The patient has the right to an explanation of charges for equipment and supplies.
(8) Quality assurance:
(A) There is an ongoing continuous quality improvement program designed to monitor and evaluate the quality of patient care, improvement of patient services, if applicable, and resolution of identified problems.
(B) Continuous quality improvement activities are defined in a written plan.
(C) Issues monitored should be determined by evaluating all complaints or incidents and items that are high volume, high risk or problem prone.
(1) Liability insurance coverage for products provided and operations of each licensed entity is required in the amount of at least $500,000.

(b) Prohibited Practices -- The following practices are prohibited:
(1) Patient freedom of choice:
Participation in any plan, agreement, or arrangement which eliminates the patient's right to select a provider, licensed under this act, of their choice shall be considered a violation of this regulation.
(2) Bribes, kickbacks and rebates:
It shall be considered a violation of this regulation for anyone to knowingly and willfully offer, pay, solicit or receive any payment in return for referring an individual to another person for the furnishing, or arranging for the furnishing, of any item or service covered by this regulation. (10/13/95, amended 8/23/96)

08-02—WHOLESALE DISTRIBUTOR OF LIST I CHEMICALS

08-02-0001—DEFINITIONS

As used in this regulation unless the context otherwise requires
(b) "Board" means the Arkansas State Board of Pharmacy;
(c) "Person" includes an individual, general or limited partnership, corporation, business firm, limited liability company, and association;
(d) "List I chemical" means ephedrine, pseudoephedrine, or phenylpropanolamine, or their salts, optical isomers and salts of optical isomers, alone or in a mixture.
(e) "Manufacturer" means anyone who is engaged in manufacturing, preparing, propagating, compounding, processing, packaging, repackaging, or labeling of a List I chemical;

(f) "Wholesale distribution" means the distribution of List I chemicals to persons other than consumers or patients, but does not include entities exempt by Arkansas Code Annotated §5-64-1006 as amended by Act 1209 of 2001.

(g) "Wholesale distributor" means any person engaged in wholesale distribution of List I chemicals; including but not limited to manufacturers; repackers; own-label distributors; private label distributors; jobbers; brokers; warehouses—including manufacturers' and distributors' warehouses, chain drug warehouses, and wholesale drug warehouses; independent wholesale drug traders; List I chemical repackagers; physicians; dentists, veterinarians; clinics; individuals; hospitals; nursing homes and their providers; and retail and hospital pharmacies that conduct wholesale distributions. A wholesale distributor shall not include any for-hire carrier or person or entity hired solely to transport List I chemicals.

08-02-0002—WHOLESALE DISTRIBUTOR OF LIST I CHEMICALS—PERMIT REQUIRED

(a) Every wholesale distributor who shall engage in the wholesale distribution of List I chemicals to include without limitation, manufacturing in this state, shipping in or into this state, or selling or offering to sell in this state, if not exempt by Act 1209 of 2001, shall register annually with the Arkansas State Board of Pharmacy by application for a permit on a form furnished by the Board and accompanied by a fee as defined in regulation 01-00-0007. The Board may require a separate permit for each facility directly or indirectly owned or operated by the same business entity or for a parent entity with divisions, subdivision, subsidiaries, and/or affiliate companies when operations are conducted at more than one location and there exists joint ownership and control among all the entities.

(b) The permit shall be renewed as defined in regulation 01-00-0007.

(c) All permits issued under this section shall expire as defined in regulation 01-00-0007.

(d) A change of ownership of a wholesale distributor of List I chemicals occurs under, but is not limited to, the following circumstances:

(1) A change of ownership of a wholesale distributor of List I chemicals owned by a *sole proprietor* is deemed to have occurred when:

(A) The business is sold and the sale becomes final or the new owner assumes control of the wholesale distributor -- which ever occurs first.

(B) The proprietor enters into a partnership with another individual or business entity.

(2) A change of ownership of a wholesale distributor of List I chemicals, owned by *partnership*, is deemed to have occurred when:

(A) There is an addition or deletion of one or more partners in a partnership to which a List I chemical wholesale distributor's permit has been issued.

(B) The business is sold and the sale becomes final or the new owner assumes control of the wholesale distributor of List I chemicals -- which ever occurs first.

(3) A change of ownership of a wholesale distributor, owned by a *corporation*, is deemed to have occurred when:

(A) An individual or business acquires or disposes of twenty percent (20%) of the corporation's outstanding shares of voting stock. (This shall not apply to any corporation the voting stock of which is actively traded on any securities exchange or in any over the counter market); or

(B) The corporation merges with another business or corporation. (The corporation owning the wholesale distributor is required to notify the Arkansas State Board of Pharmacy if a

change of ownership or merger occurs within the parent corporation of the corporation which owns the wholesale distributor); or

(C) The corporation's charter expires or is forfeited.

(D) The business is sold and the sale becomes final or the new owner assumes control of the wholesale distributor -- which ever occurs first.

(4) A change of ownership of a wholesale distributor of List I chemicals, owned by a *limited liability company*, is deemed to have occurred when:

(A) There is an addition or deletion of one or more members of the limited liability company to which a List I chemical wholesale distributor's permit has been issued;

(B) The assets of the limited liability company devoted to or utilized in the wholesale distribution of List I chemicals are sold and the sale becomes final or new owner assumes control of the wholesale distribution of List I chemicals;

(C) There is dissolution of the limited liability company.

(e)

(1) The Board may, after notice and hearing suspend or revoke the registration of a List I wholesale distributor, or impose other disciplinary action pursuant to A.C.A § 17-92-315, upon a finding of any of the following:

(A) Violation of or failure to maintain qualification under Regulation 08-02-0001 et seq.

(B) Violation of any federal, state, or local law or regulation regarding List I chemicals.

(C) Revocation, suspension, or surrender of a license or other authority issued by the Drug Enforcement Administration as a List I wholesale distributor or to otherwise possess, distribute or sell or offer to distribute or sell List I chemicals

(2) The Board shall follow the same procedures for hearings for a List I chemical wholesale distributor as applicable to hearings for pharmacists as set forth in § 17-92-101 et seq. and Board regulations.

08-02-0003—MINIMUM REQUIRED INFORMATION FOR OBTAINING A PERMIT

(a) The Arkansas Board of Pharmacy requires the following from each wholesale drug distributor of List I chemicals as part of the initial registration procedure and as part of any renewal of such permit:

(1) The name, full business address, and telephone number of the permit holder;

(2) All trade or business names used by the permit holder;

(3) Addresses, telephone numbers, and the names of contact persons for the facility used by the permit for the storage, handling, and distribution of List I chemicals;

(4) The type of ownership or operation (i.e. partnership, corporation, or sole proprietorship); and

(5) The name(s) of the owner and/or operator of the permit holder, including:

(A) If a person, the name of the person;

(B) If a partnership, the name of each partner, and the name of the partnership;

(C) If a corporation, the name and title of each corporate officer and director, the corporate names, and the name of the state of incorporation, and the name of the parent company, if any;

(D) If a sole proprietorship, the full name of the sole proprietor and the name of the business entity.

(E) If a limited liability company, the name and state of organization of the limited liability company, the name of each member and manager of the limited liability company.

(b) Where operations are conducted at more than one location, by a single wholesale distributor of List I chemicals, each such location shall obtain a permit issued by the Arkansas State Board of Pharmacy.
(c) Changes in any information on the application for licensure shall be submitted to the Arkansas State Board of Pharmacy within thirty (30) days after such a change.

08-02-0004—MINIMUM QUALIFICATIONS

(a) The Arkansas State Board of Pharmacy will consider the following factors in determining eligibility for obtaining a permit as a Wholesale Distributor of List I chemicals.
  (1) Any convictions of the applicant under any federal, state or local laws or regulations pertaining to wholesale or retail drug distribution of List I chemicals, distribution of controlled substances, or distribution of prescription drugs;
  (2) Any felony convictions of the applicant under federal, state or local laws;
  (3) The applicant's past experience in the manufacture or distribution of List I chemicals, prescription drugs, or controlled substances;
  (4) The furnishing, by the applicant, of false or fraudulent material in any application made in connection with manufacturing or distribution of List I chemicals, prescription drugs, or controlled substances;
  (5) Suspension or revocation by federal, state or local government of any permit currently or previously held by the applicant for the manufacture or distribution of any drugs or List I chemicals, prescription drugs, or controlled substances;
  (6) Compliance with registration requirements under previously granted permits, if any;
  (7) Compliance with the requirements to maintain and/or make available to the State Board of Pharmacy or to federal, state or local law enforcement officials those records required to be maintained by wholesale drug distributors of List I chemicals;
  (8) Any other factors or qualifications the Arkansas Board of Pharmacy considers relevant to and consistent with the public health and safety.

(b) The applicant shall be registered with the Drug Enforcement Administration (DEA) as a retail distributor of List I Chemicals and said registration shall be in good standing.

~~(b)~~(c)The Arkansas Board of Pharmacy reserves the right to deny a permit to an applicant if it determines that the granting of such a permit would not be in the public interest.

08-02-0005—PERSONNEL

The wholesale distributor of List I chemicals that is issued a permit by the Board of Pharmacy shall employ adequate personnel with the education and experience necessary to safely and lawfully engage in the wholesale distribution of List I chemicals.

08-02-0006—MINIMUM REQUIREMENTS FOR THE STORAGE AND HANDLING OF LIST I CHEMICALS

The following are required for the storage and handling of List chemicals, by wholesale drug distributors and their officers, agents, representatives, and employees.

(a) Facilities.

All facilities at which List I chemicals are stored, warehoused, handled, held, offered, marketed or displayed shall:

  (1) Be of suitable size and construction to facilitate cleaning, maintenance, and proper operation;